

Paul E. Harris and Charles Hesdorffer  
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REMARKS

Claims 1-5, 8-11 and 13 were pending, with claims 6, 7 and 12 having previously been canceled, without prejudice or disclaimer. By this Amendment, claims 8 and 13 have been canceled, and claims 1 and 2 have been amended by adding features formerly recited in claim 8 (now canceled) and to clarify the claimed invention. No new matter and no new issues are introduced by the amended claims. Accordingly, claims 1-5, and 9-11 are now pending, with claims 1 and 2 being in independent form.

Rejection under 35 U.S.C. §112, first paragraph

In Section 4 of the February 1, 2005 final Office Action, claims 1-5, 8-11 and 13 were rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The Examiner stated that the instant invention is drawn to a method of "reproducibly generating dendritic cells (DCs)" comprising a method of cell culture. The Examiner further stated that the in vitro generation of dendritic cells was well known in the art at the time of the invention of the instant claims, however, performing the steps of the instant claims would not necessarily result in a product consisting of said cells given the breadth of the claims, i.e., the lack of specific limitation. The Examiner also stated that the method of the instant claims must be considered highly unpredictable and requiring of undue experimentation.

The Examiner stated that step (d) comprises the actual culturing of adherent monocytes to produce DCs. The Examiner further

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stated that the method comprises a method of culturing human DC, the incubation of the adherent monocytes would require the inclusion of specific reagents in the incubation, at minimum GM-CSF and IL-4 or IL-7.

The Examiner stated that no amendment to part d), the step presumed by the Examiner to comprise the culture of the cells, has been made that includes the culture of monocytes and/or monocyte precursors in the required cytokines. The Examiner further stated that "further processing the contents of the cell culture container" does not necessarily comprise either culturing or processing employing cytokines.

By this Amendment, claims 8 and 13 have been canceled, and claims 1 and 2 have been amended by adding features formerly recited in claim 8 (now canceled) and to clarify the claimed invention.

Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the rejection of the claims under 35 U.S.C. § 112, first paragraph.

**Rejection under 35 U.S.C. §112, first paragraph**

In Section 6 of the February 1, 2005 final Office Action, claims 1-5, 8-11 and 13 were rejected under 35 U.S.C. §112, first paragraph, as allegedly the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. The Examiner stated that this a new matter rejection.

The Examiner stated that the specification and the claims as

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originally filed do not provide support for the invention as now claims, specifically:

- A) "obtaining blood mononuclear cells through apheresis with monocytes and monocyte precursors being separated substantially from lymphocytes ... [and culturing in media] ... said media including at least rh-GM-CSF and at least one of rh-IL-4 or rh-IL-7 reagents" (step a);
- B) "further processing the contents of the cell culture container which remain in the container after step (c) and harvesting the dendritic cells from the contents" (step d); and
- C) in claim 13, step (b), "incubating the contents of the cell culture container, including the medium and the blood mononuclear cells loaded into the cell culture container in step (a), for culturing, allowing beads with adherent cells attached thereto after incubation to settle, and then expressing off supernatant including nonadherent cells".

The Examiner stated that Applicants do not indicate that no new matter has been added and do not indicate where support for the new limitation can be found in the specification.

The Examiner stated that a review of the specification shows that the generic method of the claims is disclosed only briefly starting at line 25 of page 4 through the top half of page 6. The Examiner further stated that beginning at line 15 of page 6 through line 20 of page 12 is what consists essentially of a specific example. The Examiner also stated that at line 21 of page 12 through the end of the specification is a description of the beads, containers, and quality control employed in the claimed method.

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The Examiner stated that Applicant is advised that individual specific parameters disclosed only in the specific example cannot now be recited in the generic method of the instant claims without introducing new matter into the claims.

The Examiner stated that regarding parameters such as those of part A) above, obtaining blood mononuclear cells through apheresis is only disclosed from G-CSF mobilized donors. The Examiner further stated that the claims reciting obtaining blood mononuclear cells through apheresis from any donor is broader than the disclosure of the instant specification and thus, comprises the introduction of new matter into the claims. The Examiner also stated that the specification teaches only the separation of monocytes and monocyte precursors from red blood cells, lymphocytes, and platelets, and not the separation of monocytes and monocyte precursors from lymphocytes alone and this limitation again comprises the introduction of new matter, i.e., matter not disclosed in the specification, into the claims.

By this Amendment, claims 8 and 13 have been canceled, and claims 1 and 2 have been amended by adding features formerly recited in claim 8 (now canceled) and to clarify the claimed invention.

Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the rejection of the claims under 35 U.S.C. § 112, first paragraph.

Rejection under 35 U.S.C. §112, second paragraph

In Section 8 of the February 1, 2005 final Office Action, claims 1-5, 8-11 and 13 were rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite for failing to particularly

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point out and distinctly claim the subject matter which applicant regards as the invention.

The Examiner stated that in claims 1, 2 and 13, the recitation of "obtaining blood mononuclear cells through apheresis with monocytes and monocyte precursors being separated substantially from lymphocytes, and loading blood mononuclear cells into a cell culture container" is vague and indefinite as both of the fractions obtained, i.e., the monocyte and monocyte precursor fraction and the lymphocyte fraction, comprise blood mononuclear cells. The Examiner further stated that it is unclear which cell fraction is being employed in the claimed method.

By this Amendment, claims 8 and 13 have been canceled, and claims 1 and 2 have been amended by adding features formerly recited in claim 8 (now canceled) and to clarify the claimed invention.

Accordingly, Applicants respectfully requests that the Examiner reconsider and withdraw the rejection of the claims under 35 U.S.C. §112, second paragraph.

In view of the amendments to the claims and remarks hereinabove, Applicants maintain that claims 1-5, and 9-11 are now in condition for allowance. Accordingly, Applicants earnestly solicit the allowance of the application.

If a telephone interview would be of assistance in advancing prosecution of the subject application, Applicants' undersigned attorneys invite the Examiner to telephone them at the telephone number provided below.

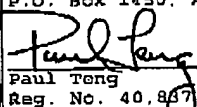
If a petition for an extension of time is required to make this

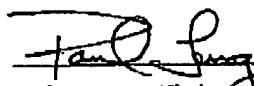
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response timely, this paper should be considered to be such a petition.

No fee is deemed necessary in connection with the filing of this Amendment. However, if any fees are required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,

I hereby certify that this correspondence is being transmitted by facsimile to the USPTO and is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop AP, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.	
 Paul Teng Reg. No. 40,837	April 28, 2005 Date

  
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